This document is scheduled to be published in the Federal Register on 09/08/2022 and available online at **federalregister.gov/d/2022-19410**, and on **govinfo.gov**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1275]

General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance for industry entitled "General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products," replacing the December 2014 draft guidance of the same name. This draft guidance, once finalized, will assist sponsors of investigational new drug applications (INDs) and applicants of new drug applications (NDAs), biologics license applications (BLAs), and supplements to such applications, who are planning to conduct clinical studies in pediatric populations. In addition, this draft guidance, once finalized, will assist investigators in the design and planning of, and Institutional Review Boards in the assessment of, clinical studies in pediatric populations.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-D-1275 for "General Clinical Pharmacology Considerations for Pediatric Studies of Drugs and Biological Products." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a

written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the

SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elimika Pfuma Fletcher, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2162, Silver Spring, MD 20993, 301-796-3473, Elimika.Fletcher@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "General Clinical Pharmacology Considerations for Pediatric Studies of Drugs, Including Biological Products." Effectiveness, safety, or dose-finding studies in pediatric patients involve gathering clinical pharmacology information, such as information regarding a product's pharmacokinetics and pharmacodynamics, to inform dose selection and individualization. This draft guidance addresses general clinical pharmacology considerations for conducting studies so that the dosing and safety information for drugs and biological products in pediatric populations can be sufficiently characterized, leading to well-designed trials to evaluate effectiveness.

In general, this draft guidance focuses on the clinical pharmacology information (e.g., exposure-response, pharmacokinetics, and pharmacodynamics) that supports findings of effectiveness and safety and helps identify appropriate doses in pediatric populations. This draft guidance also describes how quantitative approaches (i.e., pharmacometrics) can use disease and exposure-response knowledge from relevant prior clinical studies to help design and evaluate future pediatric studies.

This draft guidance revises the draft guidance, "General Clinical Pharmacology Considerations for Pediatric Studies of Drugs and Biological Products," issued on December 9, 2014 (79 FR 73079). This draft guidance provides clarification on clinical pharmacology studies in pediatric patients from the 2014 draft guidance in response to public comments.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "General Clinical Pharmacology Considerations for Pediatric Studies of Drugs and Biological Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved FDA collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information for the submission of new drug applications in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collections of information for the submission of biologics license applications in 21 CFR part 601 have been approved under OMB control number 0910-0338. The collections of information for the submission of investigational new drug applications in 21 CFR part 312 have been approved under OMB control number 0910-0014. The collections of information for the protection of human subjects and institutional review boards in parts 21 CFR parts 50 and 56 have been approved under OMB control number 0910-0130. The collections of information for the submission of prescription drug product labeling in 21 CFR 201.56 and 201.57 have been approved under OMB control number 0910-0572. The collections of information in 21 CFR 312.47 and 312.82 for requesting meetings with FDA about drug development programs have been approved under OMB control number 0910-0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,

https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.regulations.gov.

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-19410 Filed: 9/7/2022 8:45 am; Publication Date: 9/8/2022]